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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,942	GUPTA, AJAY	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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OFFICIAL ACTION

Status of Claims

Claims 1-4 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of treating iron deficiency in a mammal, does not reasonably provide sufficient enablement to one of ordinary skill in the art as to preventing or curing iron deficiency in a mammal, as broadly claimed, without an undue amount of experimentation.

An analysis of whether the scope of a particular claim is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d 1438, 1444 (Fed. Cir. 1991). More particularly, there are many factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be "undue." See *In re Wands* at page 1404. MPEP § 2164.01(a). The Court in *In re Wands* set forth the following factors to be considered, which include, without limitation, the: 1. scope or breadth of the claims; 2. nature of the invention; 3. relative level of skill possessed by one of ordinary skill in the art; 4. state of, or the amount of knowledge in, the prior art; 5. level or degree of predictability, or a lack thereof, in the art; 6. amount of guidance or direction provided by the inventor; 7. presence or absence of working examples; and 8. quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure.

The specification merely discloses, without more, that iron deficiency may be treated by administering a therapeutically effective amount of ferric pyrophosphate to a mammal in need thereof. However, Applicant is purporting to prevent or cure a pathological manifestation and clinical presentation of iron deficiency in a mammal suffering therefrom or susceptible thereto. As a result, the claims are broader in scope than the enabling disclosure.

The nature of the invention is directed a method of preventing or curing iron deficiency in a mammal suffering therefrom or susceptible thereto.

The relative level of skill possessed by one of ordinary skill in the art of formulating compositions for not only treating, but also attempting to discover a prevention or cure for, iron

deficiency in a mammal is relatively high, as a majority of lead investigators conducting scientific research and development in this particular technological area, as of the effective filing date of the instant application, possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

An extraordinary degree of unpredictability, not to mention a great deal of uncertainty due to a distinct lack of knowledge of the skilled artisan, existed in the state of the prior art regarding how to absolutely prevent or cure iron deficiency in a mammal.

Since a great deal of uncertainty due to a distinct lack of knowledge of the skilled artisan existed in the state of the art at the time the instant application was filed, and because there was an extremely low level or degree of predictability in the art as of the effective filing date of the instant application, the Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a method for treating iron deficiency in a mammal, the specification utterly fails to provide scientific data and working embodiments with respect to a method of absolutely preventing or curing iron deficiency in a mammal.

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the method of the instant application does in fact prevent or cure iron deficiency in a mammal.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the prevention

of iron deficiency in a mammal utilizing said method, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method would in fact actually prevent or cure iron deficiency in a mammal.

"Prevention" is defined in Webster's New World Dictionary as "to keep from happening; make impossible by prior action." See, Webster's New World Dictionary, 3rd College Ed., Webster's New World Dictionary Publishing, page 1067-1068 (1988). Applicant is advised that although claim language, such as "preventing" or "curing" lack enablement under 35 U.S.C. § 112, first paragraph, phrases such as "reducing the incidence," "reducing the frequency" or "reducing the likelihood," etc., are considered by the Office to be enabling, assuming of course that the specification in question has adequate written description and support for the asserted and claimed utility.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the meets and bounds of the instantly claimed invention as currently defined in claim 4 is unclear since confusion exists as to whether the Applicant is claiming a method of treating iron deficiency in a mammal by parenterally (i.e., intravenously or

intramuscularly) administering ferric pyrophosphate at a rate of about 40 mg per hour for an indefinite period of time and regardless of the body weight of said mammal, or alternatively whether there is an unspecified, predetermined and/or crucial period of time in which ferric pyrophosphate can continuously and safely be administered to a mammal of a certain body weight at a rate of about 40 mg per hour without running the risk of serious and dangerous side-effects, life-threatening complications, toxic poisoning (i.e., hyperferremia) and/or iron overdose. Applicant is respectfully reminded that upon amending said claim to overcome the aforementioned indefiniteness rejection, Applicant must not introduce new matter, which lacks support within the instant specification as originally filed.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,447,732 (hereinafter the Tanimoto '732 patent).

Similar to claims 1-3 of the instant application, the Tanimoto '732 patent discloses a method of treating iron deficiency in a mammal (column 3, lines 14-15; and column 13, lines 51-61) comprising parenterally administering a therapeutically effective amount (column 5, lines 66-68) of ferric pyrophosphate (column 3, lines 67-68; and column 4, lines 1-3 and 15-17) to

said mammal in need thereof; wherein said parenteral administration is an intravenous route of administration (column 6, lines 21-24).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the Tanimoto '732 patent.

Similar to claim 4 of the instant application, the Tanimoto '732 patent teaches a method of treating iron deficiency in a mammal comprising parenterally administering a therapeutically effective amount of ferric pyrophosphate to said mammal in need thereof; wherein said parenteral administration is an intravenous route of administration; wherein said therapeutically effective amount of ferric pyrophosphate is administered to said mammal at a rate of about 0.5 mg to about 1000 mg per serving (column 5, lines 66-68). It would have been obvious to one of ordinary skill in the art (especially when taking into consideration other extremely important factors such as body weight and time of administration) to administer ferric pyrophosphate at a rate significantly less than 1000 mg per hour when the route of administration of said ferric pyrophosphate is accomplished parenterally (i.e., intravenously or intramuscularly), as opposed

to orally, so as to thereby avoid inducing or running the risk of serious and dangerous side-effects, life-threatening complications, toxic poisoning (i.e., hyperferremia) and/or iron overdose. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references.

2. Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of the Tanimoto '732 patent and U.S. Patent 4,315,942 (hereinafter the Cordon '942 patent).

Similar to claim 4 of the instant application, the Tanimoto '732 patent teaches a method of treating iron deficiency in a mammal comprising parenterally administering a therapeutically effective amount of ferric pyrophosphate to said mammal in need thereof; wherein said parenteral administration is an intravenous route of administration; wherein said therapeutically effective amount of ferric pyrophosphate is administered to said mammal at a rate of about 0.5 mg to about 1000 mg per serving (column 5, lines 66-68).

Likewise, the Cordon '942 patent teaches a method of treating iron deficiency in a mammal (column 3, lines 61-64) comprising parenterally administering a therapeutically effective amount (column 2, lines 62-68; and column 3, lines 1-14) of any conventional, water soluble, physiologically acceptable ferric salt (column 3, lines 31-39) to said mammal in need thereof; wherein said parenteral administration is an intravenous or intramuscular route of administration (column 1, lines 6-8 and 61-65); wherein said therapeutically effective amount of said conventional, water soluble, physiologically acceptable ferric salt is administered to said

mammal at a rate of about 100 mg to about 600 mg per kg of body weight per day when administer intravenously, or at a rate of about 100 mg to about 600 mg per kg of body weight per day when administered intramuscularly (column 2, lines 62-68; and column 3, lines 1-14).

Based on the combined teachings of the aforementioned prior art references, it would have been obvious to one of ordinary skill in the art to treat iron deficiency in a mammal by intravenously administering a therapeutically effective amount of ferric pyrophosphate at a rate of about 40 mg per hour to said mammal. Sufficient motivation, as well as a reasonable expectation of success, exists to combine the aforementioned cited prior art references as both references collectively teach treating iron deficiency in a mammal by intravenously administering a therapeutically effective amount of a conventional, water soluble, physiologically acceptable ferric salt, such as ferric pyrophosphate for example. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because each and every element of the claimed invention, as a whole, would have been reasonably disclosed or suggested by the teachings of the cited prior art references

Conclusion

Claims 1-4 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

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